

Ultrasonic Table Doppler

Sonotrax Pro 2



PT. SINKO PRIMA ALLOY

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About this Manual

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Statement

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Terms Used in this Manual

This guide is designed to give key concepts on safety precautions.

WARNING

A **WARNING** label advises against certain actions or situations that could result in personal injury or death.

A3.2 Overall Sensitivity of SONOTRAX PRO 2 (3MHz Wired Probe)

Diameter of Target Reflector (mm)	Distance (d/mm)	Reflection Loss A(d)	Two-way Attenuation $B = \sum B_x + B_w$						$V_s(r.m.s)$ mV	$V_d(r.m.s)$ mV	$\frac{dV_s(r.m.s)}{dV_d(r.m.s)}$ dB	Overall Sensitivity (S=A(d)+B+C) dB	
			T	6#	3#	-	-	B_x (dB)	B (dB)				
1.58 A=44.5dB@ 3MHz	50	44.5	T	6#	13.5	-	-	0	57.1	167.3	82.44	6.15	107.8
	75	44.5	T	6#	3#	-	-	0	57.1	162.4	82.28	5.91	107.5
	100	44.5	T	6#	2#	-	-	0	53.2	159.8	81.56	5.84	103.5
	200	44.5	T	6#	1#	-	-	0	50.1	155.7	81.74	5.60	100.2
	50	42.0	T	6#	3#	-	-	0	57.1	164.0	82.52	5.97	105.1
	75	42.0	T	6#	2#	-	-	0	53.2	161.8	82.16	5.89	101.1
	100	42.0	T	6#	2#	-	-	0	53.2	160.4	81.96	5.83	101.0
	200	42.0	T	6#	1#	-	-	0	50.1	159.7	82.02	5.79	97.9
Doppler Frequency (Hz)			500						Velocity of Target (cm/s)		12.5		

Diameter of Target Reflector (mm)	Distance (d/mm)	Reflection Loss A(d)	Two-way Attenuation $B = \sum B_x + B_w$						$V_s(r.m.s)$ mV	$V_d(r.m.s)$ mV	$\frac{dV_s(r.m.s)}{dV_d(r.m.s)}$ dB	Overall Sensitivity (S=A(d)+B+C) dB	
			T	6#	3#	-	-	B_x (dB)	B (dB)				
1.58 A=45.7dB@ 2MHz	50	45.7	T	6#	24.9	7.7	-	0	57.5	168.6	84.32	6.02	109.2
	75	45.7	T	6#	2#	5.5	-	0	55.3	164.2	83.88	5.83	106.8
	100	45.7	T	6#	6#	1#	-	0	53.5	165.6	84.58	5.84	105.0
	200	45.7	T	6#	6#	3.7	-	0	49.8	167.0	84.34	5.93	101.4
	50	43.2	T	6#	6#	3#	-	0	57.5	168.8	84.56	6.00	106.7
	75	43.2	T	6#	6#	3#	-	0	57.5	166.1	84.14	5.91	106.6
	100	43.2	T	6#	6#	2#	-	0	55.3	164.2	83.90	5.83	104.3
	200	43.2	T	6#	6#	1#	-	0	53.5	162.9	84.06	5.75	102.5
Doppler Frequency (Hz)			333						Velocity of Target (cm/s)		12.5		

Diameter of Target Reflector (mm)	Distance (d/mm)	Reflection Loss A(d)	Two-way Attenuation $B = \sum B_x + B_w$						$V_s(r.m.s)$ mV	$V_d(r.m.s)$ mV	$\frac{dV_s(r.m.s)}{dV_d(r.m.s)}$ dB	Overall Sensitivity (S=A(d)+B+C) dB	
			T	6#	3#	-	-	B_x (dB)	B (dB)				
1.58 A=44.5dB@ 3MHz	50	44.5	T	6#	13.5	-	-	0	57.1	155.7	78.56	5.94	107.5
	75	44.5	T	6#	3#	-	-	0	57.1	154.9	78.30	5.93	107.5
	100	44.5	T	6#	2#	-	-	0	53.2	152.1	77.94	5.81	103.5
	200	44.5	T	6#	1#	-	-	0	50.1	151.2	78.42	5.70	100.3
	50	42.0	T	6#	13.5	-	-	0	57.1	153.5	78.46	5.83	104.9
	75	42.0	T	6#	2#	-	-	0	53.2	153.2	78.72	5.78	101.0
	100	42.0	T	6#	9.6	-	-	0	53.2	150.8	78.02	5.72	100.9
	200	44.5	T	6#	1#	-	-	0	50.1	155.3	78.44	5.93	98.0
Doppler Frequency (Hz)			500						Velocity of Target (cm/s)		12.5		

Appendix 3 Overall Sensitivity

A3.1 Overall Sensitivity of SONOTRAX PRO 2 (2MHz Wired Probe)

CAUTION

A CAUTION label advises against actions or situations that could damage equipment, produce inaccurate data, or invalidate a procedure.

NOTE

A NOTE provides useful information regarding a function or a procedure.

Diameter of Target Reflector (mm)	Distance (d) (mm)	Reflection Loss A(d)	Two-way Attenuation $B = \sum B_s + B_w$					$\frac{V_s(r.m.s)^2}{V_t(r.m.s)^2}$ dB	Overall Sensitivity (S=A(d)+B+C) dB				
			T	6#	6#	3#	-						
1.58 A=45.7dB @ 2MHz	50	45.7	T	6#	24.9	7.7	-	0	57.5	184.6	91.26	6.12	109.3
	75	45.7	T	6#	6#	2#	-	0	55.3	178.2	88.96	6.03	107.0
	100	45.7	T	6#	6#	1#	-	0	53.5	174.4	90.04	5.74	104.9
	200	45.7	T	6#	6#	-	-	0	49.8	173.0	89.56	5.72	101.2
2.38 A=43.2dB @ 2MHz	50	43.2	T	6#	6#	2#	1#	0	59.0	184.8	90.96	6.30	108.5
	75	43.2	T	6#	6#	3#	-	0	57.5	176.2	89.48	5.89	106.6
	100	43.2	T	6#	6#	2#	-	0	55.3	181.8	90.20	6.09	104.6
	200	43.2	T	6#	6#	1#	-	0	53.5	176.4	90.24	5.82	102.5
Doppler Frequency (Hz)			333				Velocity of Target (cm/s)	12.5					

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A2.4 Recommended separation distances between portable and mobile RF communication equipment and the EQUIPMENT or SYSTEM- For EQUIPMENT or SYSTEM that are not LIFE-SUPPORTING

Recommended separation distances between portable and mobile RF communications equipment and the SONOTRAX PRO 2/SONOTRAX PRO 2 BLUETOOTH			
Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d=1.2\sqrt{P}$ ($d=35\sqrt{P}$) 1.995MHz to 2.010MHz 2.985MHz to 3.015MHz)	80 MHz to 800 MHz $D=1.2\sqrt{P}$	800 MHz to 2.5 GHz $D=2.3\sqrt{P}$
0.01	0.12(3.5)	0.12	0.23
0.1	0.37(11.1)	0.37	0.73
1	1.2(35)	1.2	2.3
10	3.7(111)	3.7	7.3
100	12(350)	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

A2.3 Electromagnetic Immunity – for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

Guidance and manufacturer's declaration – electromagnetic immunity			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment -guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3Vrms (0.1Vrms 1.995MHz~2.010MHz 2.985MHz~3.015MHz)	Portable and mobile RF communications equipment should be used no closer to any part of the SONOTRAX PRO 2/SONOTRAX PRO 2 BLUETOOTH , including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $\sqrt{d=1.2 P}$ $d=3\sqrt{P}$ 1.995MHz to 2.010MHz $d=3\sqrt{P}$ 2.985MHz to 3.015MHz $d=1.2 \sqrt{80} P$ 800 MHz to 800 MHz $d=2.3 P$ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, ^a should be less than the compliance level in each frequency range. ^b Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	
<p>NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			
<p>^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the SONOTRAX PRO 2/SONOTRAX PRO 2 BLUETOOTH is used exceeds the applicable RF compliance level above, the SONOTRAX PRO 2/SONOTRAX PRO 2 BLUETOOTH should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the SONOTRAX PRO 2/SONOTRAX PRO 2 BLUETOOTH Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p> <p>^b A small black square symbol indicating potential interference.</p>			

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Chapter 1 Safety Guide

NOTE:

Familiarize yourself with this user manual before attempting to operate the Doppler.
Follow the operation and maintenance instructions to ensure proper use of it.

1.1 Safety Precautions

WARNING and **CAUTION** messages must be observed. To avoid the possibility of injury, observe the following precautions during the operation of the device.

WARNING

- 1 This device is not explosion-proof and can not be used in the presence of flammable anaesthetics.
- 2 SONOTRAX PRO 2/SONOTRAX PRO 2 BLUETOOTH Ultrasonic TableTop Doppler is a tool to aid healthcare professionals and should not be used in place of normal fetal monitoring.
- 3 This device is not intended for treatment.
- 4 Do not apply this device and other ultrasonic equipment simultaneously on a same patient, in case of possible hazard caused by leakage current superposition.
- 5 Do not touch accessible parts of non-medical electrical equipment and the patient simultaneously.
- 6 Do not apply this device simultaneously with other PATIENT-connected equipment, such as, a cardiac pacemaker or other electrical stimulators, on a same patient.
- 7 The device is not protected against defibrillation. Do not use it with HF surgical equipment.

CAUTION

- 1 Federal (U.S.) law restricts this device to sale by or on the order of a physician.
- 2 Refer servicing to qualified service personnel.
- 3 The main unit is designed for continuous operation and is 'ordinary'. It is not waterproof; do not immerse it in any liquid (i.e. not drip or splash-proof).
- 4 Keep the device clean. Avoid vibration.
- 5 Apply the SONOTRAX PRO 2/SONOTRAX PRO 2 BLUETOOTH in an environment with a temperature between +5 °C (+41 °F) and +40 °C (+104 °F).
- 6 **Electromagnetic Interference** - Ensure that the environment in which the device is operated is not subject to any source of strong electromagnetic interference, such as radio transmitters, mobile telephones, etc..

A2.2 Electromagnetic Immunity – for all EQUIPMENT and SYSTEMS

Guidance and manufacturer's declaration – electromagnetic immunity			
The SONOTRAX PRO 2/SONOTRAX PRO 2 BLUETOOTH is intended for use in the electromagnetic environment specified below. The customer or the user of SONOTRAX PRO 2/SONOTRAX PRO 2 BLUETOOTH should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment -guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines	±2kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line to line ±2 kV line to ground	±1 kV line to line ±2 kV line to ground	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60Hz) magnetic field IEC61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the SONOTRAX PRO 2/SONOTRAX PRO 2 BLUETOOTH requires continued operation during power mains interruptions, it is recommended that the SONOTRAX PRO 2/SONOTRAX PRO 2 BLUETOOTH be powered from an uninterruptible power supply or a battery.

NOTE UT is the a.c. mains voltage prior to application of the test level.

Appendix 2 EMC Information – Guidance and Manufacture's Declaration

A2.1 Electromagnetic Emissions- For all EQUIPMENT and SYSTEMS

Guidance and manufacture's declaration- electromagnetic emission		
Emission test	Compliance	Electromagnetic environment-guidance
RF emissions CISPR 11	Group 1	The SONOTRAX PRO 2/SONOTRAX PRO 2 BLUETOOTH uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	
Harmonic emissions IEC 61000-3-2	Class A	The SONOTRAX PRO 2/SONOTRAX PRO 2 BLUETOOTH is suitable for use in all establishments, other than domestic and those directly connected to the public low-voltage power supply network that supplies building used for domestic purposes.
Voltage fluctuations/flicker emissions IEC61000-3-3	Complies	

CAUTION

- 7 Check that the equipment does not have visible evidence of damage that may affect personnel's safety or examining capability before use. If damage is detected, replacement is recommended.
- 8 The device and accessories are to be disposed of according to local regulations after their useful lives. Alternatively, they can be returned to the dealer or the manufacturer for recycling or proper disposal. Batteries are hazardous waste. Do NOT dispose them together with house-hold garbage. At the end of their life hand the batteries over to the applicable collection points for the recycling of waste batteries. For more detailed information about recycling of this product or battery, please contact your local Civic Office, or the shop where you purchased the product.

1.2 Symbols

	Headphones
	Equipotentiality
	Alternating Current
	Fuse
	“ON”/“OFF” for a part of equipment
	Menu
	Recording and play back
	Graphical recorder
	Move the cursor downwards
	Move the cursor upwards
	speaker
	Minus
	Plus
	Charge battery
	Push right



Caution. Refer to accompanying documents.



Consult Instructions for Use



Type B applied part. This symbol indicates the unit is internally powered equipment, and the degree of protection against electrical shock is type B.



The symbol indicates that the device complies with the European Council Directive 93/42/EEC concerning medical devices.



The symbol indicates that the device should be sent to the special agencies according to local regulations for separate collection after its useful life.



The device is protected against splashing water. Water splashed against the enclosure from any direction shall have no harmful effects.



Part Number



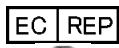
Serial Number



Date Of Manufacture



Manufacturer



Authorized Representative in the European Community



General symbol for recovery/recyclable

Rx only (U.S.)

Federal (U.S.) Law restricts this device to sale by or on the order of a physician

Appendix 1 Ordering Information

CAUTION

Only the parts supplied by the manufacturer should be used with the Doppler.

Parts	Part Number
Probe	
2 MHz Wired Probe	12.01.110744
3 MHz Wired Probe	12.01.110745
Probe Cable	01.13.036108
2 MHz Wireless Probe	12.01.110746
3 MHz Wireless Probe	12.01.110747
Accessory	
Ni-MH Battery for Main Unit	01.21.064131
Lithium Battery for Wireless Probe	11.21.064125
Earphone	01.14.104751
Carry Bag	01.56.110740
Power Cord (European Standard)	01.13.36014
Power Cord (American Standard)	11.13.36015
Security Lock	11.18.078205

8.5 Low Output Summary Table

Low Output Summary Table

(for systems with no transducers having global maximum index values exceeding 1.0)

System: Ultrasonic TableTop Doppler

Transducer Model (MHz)	$I_{spta,3}$ (mW/cm ²)	TI Type	TI Value	MI	$I_{sppa,3}$ (W/cm ²)
CW 2.0	4.742	TIS	0.03539	0.0077	0.004742
		TIB	0.08397		
CW 3.0	9.601	TIS	0.1372	0.0084	0.009601
		TIB	0.1944		
CW 4.0	40.54	TIS	0.07059	0.01408	0.04054
		TIB	0.1809		
CW 5.0	56.18	TIS	0.08824	0.01447	0.05618
		TIB	0.1904		
CW 8.0	6.673	TIS	0.1412	0.002999	0.006673
		TIB	0.04068		

Chapter 2 Introduction

2.1 Intended Use

The SONOTRAX PRO 2 Ultrasonic TableTop Doppler (hereinafter called “SONOTRAX PRO 2”) and SONOTRAX PRO 2 BLUETOOTH Ultrasonic TableTop Doppler (hereinafter called “SONOTRAX PRO 2 BLUETOOTH”) are intended to be used by health care professionals including registered nurses, practical nurses, midwives, ultrasound technicians, and physician assistants, by prescription from licensed physicians in hospitals, clinics and private offices.

The 2 MHz and/or 3 MHz obstetrical probes are indicated for the detection of fetal heart rate from early gestation thru delivery and as a general indication of fetal well being. They can also be used to verify fetal heart viability following patient trauma.

2.2 Major Parts

2.2.1 Main Unit

SONOTRAX PRO 2:



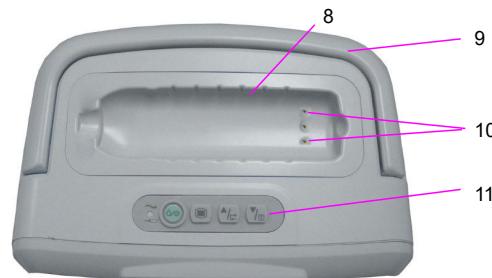


Figure 2-2 Top View of the Main Unit

WARNING

Please do not touch the probe sensor socket and the patient simultaneously.

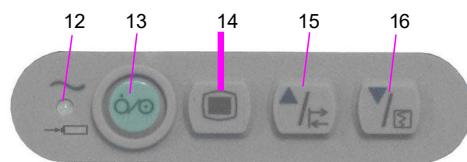


Figure 2-3 Main Unit Control Keys

- 12 Main Unit Indicator
- 13 On/OFF Key
- 14 Setup Key / Confirm Key
- 15 Up Key / Record/Play Control Key
- 16 Down Key / Print Control Key

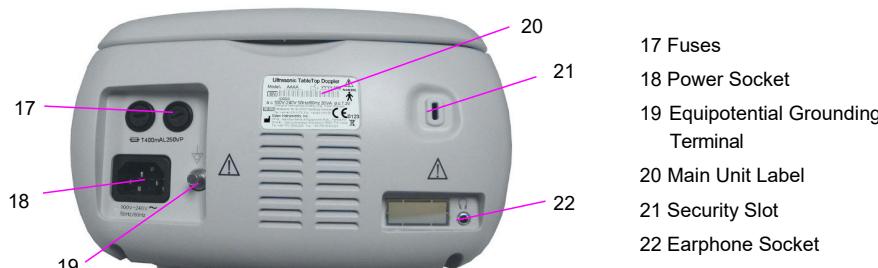


Figure 2-4 Back View of the Main Unit

Ultrasound:

Nominal Frequency:	2MHz Wired /Wireless Probes: 2MHz 3MHz Wired /Wireless Probes: 3MHz
Working Frequency:	2MHz Wired /Wireless Probes: (2.0 ± 10%)MHz 3MHz Wired /Wireless Probes: (3.0 ± 10%)MHz
2MHz Wired/wireless probe:	$I_{ob} < 10 \text{ mW/cm}^2$
3MHz Wired/wireless probe:	$p- < 1 \text{ MPa}$
	$I_{spta} < 100 \text{ mW/cm}^2$
Working Mode:	Continuous wave Doppler
Effective Radiating Area of Probe:	2MHz /3MHz Wired /Wireless probes: (245±15%)mm ²

8.4 Battery Specifications

	For main unit	For probe
Type:	Ni-MH Battery	Lithium Battery
Nominal Capacity:	2000mAh	700mAh
Nominal Voltage:	7.2V	3.7V
Charge Current (Standard):	757mA	500mA
Charge Voltage (Standard):	9V	4.2V
Necessary Charge Time	Approx. 3h	4h ~ 5h
Expected Battery Life:	Approx. 10h	Approx. 3h
Charge Mode:	Constant current/Constant voltage	
Circle Life:	≥ 300 times (after 300 circles, only 90% of the capacity can be restored.)	
Storage Temperature:	$-20^\circ\text{C} \sim +60^\circ\text{C}$ (-4 °F ~ +140 °F) (1 month) or $-20^\circ\text{C} \sim +40^\circ\text{C}$ (-4 °F ~ +104 °F) (3 months)	

Degree of Protection against Harmful Ingress of Water	Main Unit: Ordinary equipment (Sealed equipment without liquid proof) Probe: IPX4
Degree of Safety in Presence of Flammable Gases	Equipment not suitable for use in presence of flammable gases
Disinfection/Sterilizing Method	Refer to this user manual for details
EMC	CISPR 11 Group1 Class A
Earth Leakage Current (Limit):	N.C. S.F.C. 500μA 1000μA
Enclosure Leakage Current (Limit):	N.C. S.F.C. 100μA 500μA
Patient Leakage Current (Limit):	N.C. S.F.C. d.c. 10μA 50μA a.c. 10μA 50μA
Patient Auxiliary Current (Limit):	N.C. S.F.C. d.c. 10μA 50μA a.c. 10μA 50μA
Display:	Effective display area: 62.0 mm (W)x 44.0 mm(H) Number of characters: 128*64 Dots Dot size: 0.39 mm(W) x 0.55 mm(H) Dot pitch: 0.44 mm(W) x 0.60 mm(H)

8.3 Performance Specifications

FHR Performance:	FHR Measurement Range: 50bpm ~ 210bpm Resolution: 1 bpm Accuracy: ± 3 bpm
Recording and Playing:	Audio Sampling Frequency: 4KHz Recording Length: 240s
White Back Light:	Two Brightness Adjustable: OFF, ON
Audio Output Power:	2W
Auto Shut off:	1-minute/3-minute no signal and no operation



23 Battery Compartment

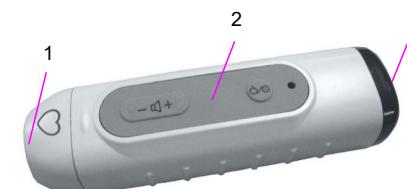
Figure 2-5 Right View of the Main Unit

NOTE:

The main unit is not waterproof. Do not immerse it in any type of liquid.

2.2.2 Probes

Wireless Probe:



- 1 Acoustic Face
- 2 Probe Control Keys
- 3 Infrared Sender
- 4 Probe Socket
- 5 Probe Cable

Wired Probe:

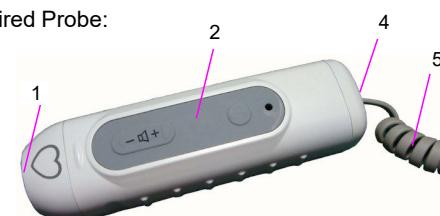


Figure 2-6 Top View of the Probe

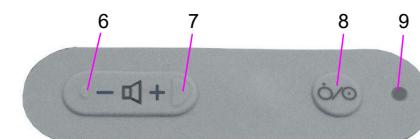


Figure 2-7 Probe Control Keys

- 6 Volume Decreasing Key
- 7 Volume Increasing Key
- 8 ON/Off Key (only available on wireless probe)
- 9 Probe Indicator

Chapter 8 Product Specifications

8.1 Environmental Specifications

Working	Temperature:	+5 °C ~ + 40 °C (+41 °F ~ +104 °F)
	Relative Humidity:	25% ~ 80%
	Atmospheric Pressure:	860hPa ~ 1060hPa
Transport and Storage	Temperature:	-20 °C ~ +55 °C (-4°F ~ +131 °F)
	Relative Humidity:	25% ~ 93%
	Atmospheric Pressure:	700hPa ~ 1060hPa

8.2 Physical Specifications

Dimensions and Weight	Dimensions:	Main Unit: 265mm x 155mm x 180 mm Probes: 140mm x 40mm x 32 mm
	Weight:	Main Unit: 1.7 kg (with battery and probe) Wireless Probe: 120 g (with battery) Wired Probe: 85 g
Power Supply	Main unit	
	Operating Voltage:	100V~240V~
	Operating Frequency:	50Hz/60Hz
	Input Power:	35VA
	Battery:	7.2V/2000mAh (Ni-MH Battery)
	Probe	
	Battery:	3.7V/700mAh (Lithium Battery)
Standards Compliance	IEC 60601-1:2005, EN 60601-1:2006, IEC 60601-1-2:2007, EN 60601-1-2:2007, IEC/EN 60601-2-37	
	Anti-electric Shock Type	Class I equipment with internal power supply
	Anti-electric Shock Degree	Type B applied parts

Chapter 7 Warranty and Service

7.1 Warranty

PT. SINKO PRIMA ALLOY warrants that PT. SINKO PRIMA ALLOY's products meet the labeled specifications of the products and will be free from defects in materials and workmanship that occur within warranty period.

The warranty is void in cases of:

- a) damage caused by mishandling during shipping.
- b) subsequent damage caused by improper use or maintenance.
- c) damage caused by alteration or repair by anyone not authorized by PT. SINKO PRIMA ALLOY.
- d) damage caused by accidents.
- e) replacement or removal of serial number label and manufacture label.

If a product covered by this warranty is determined to be defective because of defective materials, components, or workmanship, and the warranty claim is made within the warranty period, PT. SINKO PRIMA ALLOY will, at its discretion, repair or replace the defective part(s) free of charge. PT. SINKO PRIMA ALLOY will not provide a substitute product for use when the defective product is being repaired.

7.2 Contact information

If you have any question about maintenance, technical specifications or malfunctions of devices, contact your local distributor.

Alternatively, you can send an email to PT. SINKO PRIMA ALLOY service department at: sinkoprimal@gmail.com

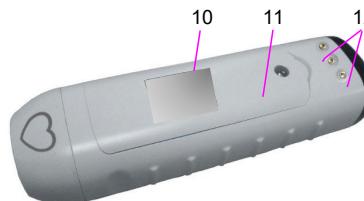


Figure 2-8 Bottom View of the Probe

- 10 Probe Type Label
- 11 Probe Battery Compartment
- 12 Probe Charge Socket

Description:

The Doppler supports 2MHz and 3MHz probes supplied by the manufacturer. The probe nominal frequency is disclosed on the probe type label.

Probes of SONOTRAX PRO 2 are wired, while probes of SONOTRAX PRO 2 BLUETOOTH are wireless.

WARNING

Do not touch the charge sockets of the Doppler probe and the patient simultaneously.

CAUTION

1. Do not immerse the probes or the probe in any liquid.
2. Do not stretch the probe cable for more than three meters.

2.2.3 Control Keys

Control keys are provided to switch on or off the device, perform the functions and change the settings.

A beep sound will be heard when you press a key of the main unit. Or you can switch off the sound. Refer to section 3.9.2 *Switching the Key Sound On and Off* for operation procedures.

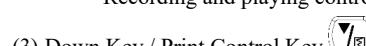


Function: Switch on/off the main unit or the probe.



Function: Move the cursor upwards / to the previous item (in the setting mode).

Recording and playing control (in the real-time examining mode).



Function: Move the cursor downwards / to the next item (in the setting mode).

Printing control (reserved).



Function: Enter setup menu (in the real-time examining mode).

Confirm selection (in the setting mode).



Function: Decrease the FHR volume (). Increase the FHR volume ().

2.2.4 Indicators

(1) Main unit indicator

The indicator of the main unit indicates the connection status of the main unit and AC power:

The indicator lights up in green – the AC power is connected.

The indicator flashes in green – the main unit is charging the main unit battery.

The indicator goes off – the AC power is not connected.

(2) Probe indicator

The indicator of the probe indicates the status of the probe:

The indicator lights up in green – the probe is switched on.

The indicator flashes in yellow when the volume control key is pressed – the volume has been decreased/increased to its minimum/maximum.

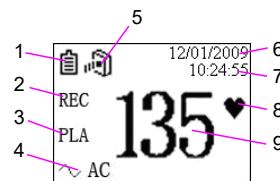
The indicator lights up continuously in yellow – the probe battery is low.

The indicator flashes in green – the probe battery is being charged.

2.2.5 LCD

The Doppler has four modes: examining mode, recording mode, playing mode and setting mode.

In the former three modes, the LCD displays as follows:



SONOTRAX PRO 2/SONOTRAX PRO 2

Handle the probe with care to avoid damaging the cover, piezoelectric crystals and mechanical movement. Do not contact the probe with hard or sharp objects.

Do not excessively flex the probe cable.

Wipe the remaining gel off the probe after use.

Keep the probes in a dry environment, where the temperature had better be lower than 45°C.

6.3 Cleaning

To clean the main unit,

Switch off the Doppler and unplug it from AC power supply. Wipe the case with a cloth that has been dampened in diluent ammonia <3%, ethanol 75% or isopropanol≤70%, and then dry it with a clean cloth. The recommended cycle is one week or when needed.

Clean the probe after each use to avoid cross infection and prolong its useful life.

To clean the probe,

Switch off the probe. Wipe it with a cloth that has been dampened in diluent ammonia <3%, ethanol 75% or isopropanol≤70%, and then dry it with a clean cloth.

CAUTION

- 1 Do not use strong solvent such as acetone.
- 2 Do not use an abrasive such as steel wool or metal polish.
- 3 Neither the main unit nor the probe is waterproof; do not immerse any part of them in liquid. Entry of liquid into the Doppler may destroy the equipment.
- 4 Do not allow any liquid remain on the surface.

6.4 Disinfection

In normal use the main unit does not need disinfection. In case of being soiled, clean the main unit case and disinfect it with 75% ethanol or isopropanol≤70% or glutaraldehyde≤3.6%.

After each use, clean the probe and disinfect it with 75% ethanol or isopropanol≤70% or glutaraldehyde≤3.6%.

CAUTION

Do not sterilize the main unit of the Doppler or the probe.

Chapter 6 Maintenance and Cleaning

6.1 Inspection

(1) Visual Inspection

Prior to using the device every time, do the following inspections:

- ◆ Check the device and accessories to see if there is any visible evidence of damage that may affect patient safety.
- ◆ Check the power socket and power cables.
- ◆ Check if the device functions properly to make sure it is in good condition.

If any damage is detected, stop using the device on the patient. Replace the damage part(s) or contact the manufacturer for service before reusing it.

(2) Routine Inspection

The overall check of the device, including safety check and function check, should be performed by qualified personnel every 6 to 12 months, and each time after service.

The equipment should undergo periodic safety testing to ensure proper patient isolation from live parts. This should include leakage current measurement and insulation testing. The recommended testing interval is once a year or as specified in the institution's test and inspection protocol.

(3) Mechanical Inspection

Make sure all exposed screws are tight.

Check the external cables for splits, cracks or signs of twisting.

Replace any cable that shows serious damage.

Pay particular attention to the supply socket.

WARNING

Failure on the part of the responsible individual hospital or institution employing the use of this equipment to implement a satisfactory maintenance schedule may cause undue equipment failure and possible health hazards.

CAUTION

The maintenance must be performed by professional personnel.

6.2 Maintenance

Avoid scratching and damaging the LCD. The gathering of dew on the LCD may occur with abrupt temperature or humidity changes. A table environment is recommended for the main unit.

Keep the exterior surface of the main unit clean, free of dust and dirt.

Item	Description	
1	Battery Indicator	 The battery is installed and the battery energy is full.  The main unit battery is low.  The main unit battery is not installed.
2	Recording Indicator: The Doppler is recording fetal heart sound. (Only in the recording mode)	
3	Playing Indicator: The Doppler is playing the recorded fetal heart sound. (Only in the playing mode)	
4	AC Indicator	 AC power is connected.
5	Infrared Indicator (Only available with SONOTRAX PRO 2 BLUETOOTH)	 Infrared signal is received.  Infrared signal is not received, indicating that poor quality signal is received.
	Probe Indicator (Only available with SONOTRAX PRO 2)	 The probe is well connected.  The probe is not connected.
6, 7	Date and Time	
8	Heart Beat Indicator: When fetal heart signal is received, the heart shape flashes to indicate the FHR refreshing frequency.	
9	FHR numeric measurement value	

In the setting mode, the LCD displays as the right figure shows.

The rectangular mark that moves up and down is called the “cursor”. Press the **Up** key or the **Down** key to move it back or forth.

Backlight

Key Sound

Auto Shut Off

Language

Chapter 3 Basic Operation

3.1 Opening Package and Checking

Open the package; take out the Doppler and accessories carefully. Place them on a flat, clean surface.

Keep the package for possible future transportation or storage. Check the components according to the packing list.

- ◆ Check for any mechanical damage.
- ◆ Check all the cables and accessories.

If there is any problem, contact us or your local distributor immediately.

3.2 Using Batteries

CAUTION

The fitting of the batteries should be carried out by the manufacturer authorized personnel. Do not remove them afterwards.

3.2.1 Fitting Main Unit Battery

The main unit is powered either by alternating current or a Ni-MH battery.

It is recommended to power the main unit solo by a battery during operation. Therefore, charge the battery fully before use to ensure enough power. Connecting to mains power supply will charge the battery no matter if the main unit is on or off.

WARNING

Switch off the Doppler and remove the power cord before fitting the main unit battery.

To fit the battery for the main unit:

- 1 Follow the arrow direction to open the battery compartment cover. The battery connecting cable & connector and the metal insert show up.

Chapter 5 Recording and Playing

The built-in recorder of the Doppler provides recording and playing fetal heart sound of 240 seconds (at most).

To record fetal heart sound,

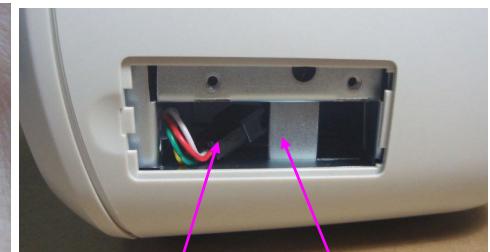
Press and hold the Record/Play control key  for two seconds. The character **REC** on the LCD lights up. Recording starts.

Press the Record/Play control key  again to stop recording and return to the real-time examining mode.

To play the fetal heart sound,

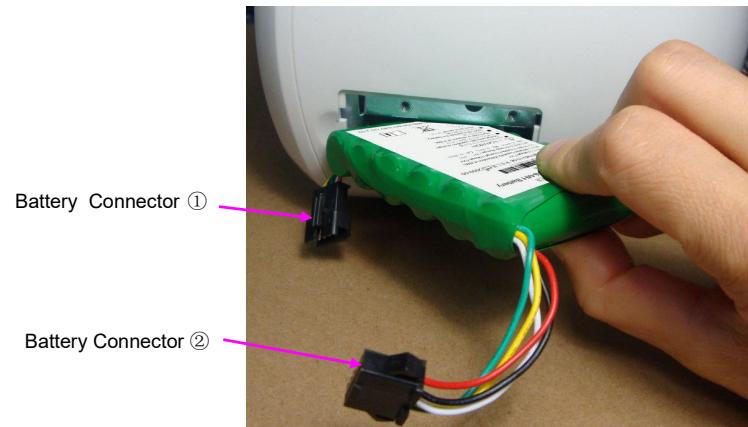
Press the Record/Play control key  in the real-time examining mode. The character **PLA** on the LCD lights up. The Doppler plays the recorded fetal heart sound.

- sender on the probe and the infrared receivers on the main unit. Aiming the infrared sender of the probe to the main unit allows the best communication result.
- 2 To avoid signal interference, do not switch on two or more SONOTRAX PRO 2 BLUETOOTH wireless probes in the same area synchronously.
 - 3 Applying SONOTRAX PRO 2 BLUETOOTH in a room of 30 m² or smaller allows the best quality. It is not recommended to

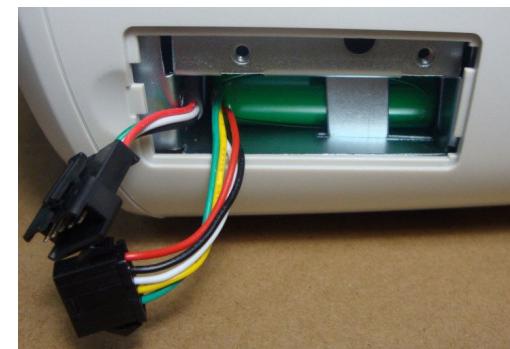


Battery Connecting Cable & Connector
Metal Insert

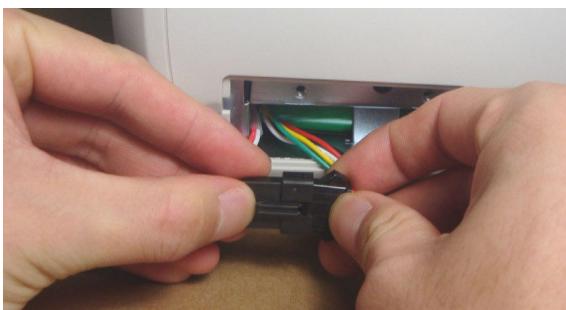
- 2 Tilt the battery sideways and put its bottom left corner into the battery compartment from the left end of the compartment to the right. Make sure connector ① stays out of the compartment.



- 3 Keep pushing the battery into the compartment until the metal insert springs back to lock the battery.



4 Connect the two connectors (①&②) and then put them into the compartment.



5 Close the battery compartment cover.



3.2.2 Fitting Wireless Probe Battery

The wireless probe is powered by a lithium battery.

To fit the battery for the probe:

- 1 Remove the screw on the battery compartment cover with a screw driver and then take the cover away with your hand.



Chapter 4 FHR Examining

WARNING

Always check if the main unit and the probe are in good condition prior to use.

CAUTION

Handle the probe with care. Do not drop it on hard surfaces.

The 2MHz and 3MHz obstetrical probes are designed for FHR examining. The 2MHz probe is optimized for deep penetration and is widely used in the third trimester pregnancy. The 3MHz probe is a general purpose probe. It has better resolution and wider detection range than the 2MHz probe, therefore is optimized for early fetal heart detection.

Follow these procedures to perform FHR examining:

- 1 Feel the position of the fetus by hand to find the best position to detect the fetal heart.
- 2 Switch on the Doppler and the probe.
- 3 Apply a small amount of coupling gel to the acoustic face of probe; place the probe face at the best position for detecting fetal heart. Angle the probe to obtain an optimum audio signal. Adjust the volume if required.

Clear fetal heart sound should be heard from the speakers/earphone, and numeric FHR value should be displayed on the LCD.

NOTE:

- 1 The best quality records will only be obtained if the probe is placed in the optimum position.
- 2 Positions with strong placental sounds or umbilical blood flow sound should be avoided.
- 3 If the fetus is in the cephalic position and the mother is supine, the clearest heart sound will normally be found on the midline below the umbilicus. During examining, the pregnant woman's prolonged lying in the supine position should be avoided owing to the possibility of supine hypotension. Sitting up or lateral positions are preferable and may be more comfortable.
- 4 It is not possible to examine FHR unless an audible fetal heart signal is detected. The fetal pulse can be distinguished from the maternal pulse by feeling the mother's pulse during the examination.

Special notes for using SONOTRAX PRO 2 BLUETOOTH:

- 1 To ensure good communication, make sure there is no barrier between the infrared

3.9.6 Setting Date Format

You can choose to switch the date on or off. When it is on, the date format has three options: DD/MM/YYYY, MM/DD/YYYY and YYYY/MM/DD.

To switch the date on and off or change date format,

- 1 Press the **Setup** key to open setup menu.
- 2 Press the **Up/Down** key to move the cursor to **Date Format**, press the **Setup** key.
- 3 Press the **Up/Down** key to toggle between **ON** and **OFF**. If you choose **ON**, the cursor moves to the date format. Select a format.
- 4 Press the **Setup** key.

NOTE:

If no operation is performed in 30 seconds, the device will also exit from the setup menu. The setting changes will not be effective.

3.10 Replacing Fuses

WARNING

Switch off the main unit and unplug it before replacing the fuses.

Two fuses are located on the rear panel of the device, their specifications are:

Size: Φ5mm*20mm; Model: T400mA250V.

When any one of the fuses is blown, perform the following steps to replace it:

1. Using a flat-head screw driver, push the fuse in for about one millimeter and then rotate it anticlockwise.
2. Remove the old fuse and replace it with a new fuse that is supplied by the manufacturer or of the same specifications.
3. Push the new fuse into the socket for about one millimeter and then rotate it clockwise back into position.

- 2 Fit the battery. Make sure the polarities correspond with the battery compartment diagram.



- 3 Close the battery compartment cover and fix it with the screw.



3.2.3 Charging Main Unit Battery

Observe the battery indicator on the LCD, the panes in it indicate the main unit battery electric energy. They go off gradually with the consumption of the battery. When the battery indicator

turns into “”, the battery power is low. You need to switch to outer AC power and charge the battery in time.

To charge the main unit battery, you need to connect the Doppler to 100V-240V~ power supply.

Connecting the main unit to power supply for approximately 3 hours will charge the battery fully, no matter if it is on or off. During this period, the main unit indicator flashes in green, and the panes in the battery indicator increase gradually. When the battery is fully charged, the indicator has four panes.

3.2.4 Charging Wireless Probe Battery

When the wireless probe battery is low, the probe power indicator turns into yellow. You need to switch off the probe and charge the battery in time.

To charge the probe battery, you need to place the probe in the probe holder. Connecting the main unit to alternating current is recommended.

It takes 4 to 5 hours to fully charge the probe battery. During this period, both the main unit indicator and the probe indicator will flash in green.

3.2.5 Care of Batteries

WARNING

- 1 Replacement of batteries shall be done at least 1.5 meters away from the patient.
- 2 Close the battery compartment before using the main unit or the probe.
- 3 Charge the battery with specified charger only.
- 4 Do not expose the batteries to high temperatures, heat them or dispose of them in fire.
- 5 Do not disassemble the batteries.
- 6 Short circuit should be avoided.

CAUTION

- 1 Keep the batteries in a cool and dry environment. The environment temperature must not exceed the range of -20°C ~ +40°C (-4°F ~ +104°F).
- 2 If the Doppler is not used for an extended period, charge the batteries at least once a month.
- 3 The batteries must be properly disposed according to local regulations after their useful life.

3.3 Connecting the Power Cable

Apply the power cable provided with the Doppler. Put the connector of the power cord to the power socket on the Doppler (figure 2-4). Put the plug of the power cord into a grounded 3-slot power output special for hospital usage.

NOTE:

Make sure the AC power supply of the Doppler complies with the following specification:
100V-240V~, 50Hz/60Hz.

WARNING

If the protective grounding (protective earth) system is doubtful, the power of the Doppler must be supplied only by inner power.

3.4 Using Wired Probe

3.4.1 Probe Socket

SONOTRAX PRO 2 adopts wired probes. The probe cable is a telephone cable with a standard RJ11 plug on each terminal.

3.9 Changing Doppler Settings

3.9.1 Switching Backlight On and Off

- 1 Press the **Setup** key to open setup menu.
- 2 Press the **Setup** key when the cursor stays at **Backlight**.
- 3 Press the **Up/Down** key to toggle between **ON** and **OFF**.
- 4 Press the **Setup** key.

3.9.2 Switching Key Sound On and Off

- 1 Press the **Setup** key to open setup menu.
- 2 Press the **Up/Down** key to move the cursor to **Key Sound**, press the **Setup** key.
- 3 Press the **Up/Down** key to toggle between **ON** and **OFF**.
- 4 Press the **Setup** key.

3.9.3 Setting Auto-Shut-Off Time

The Auto-Shut-Off feature facilitates the economical use of the Doppler. The main unit will switch off automatically after no signal is received and no operation is performed for 1 minute, 3 minutes or infinite time.

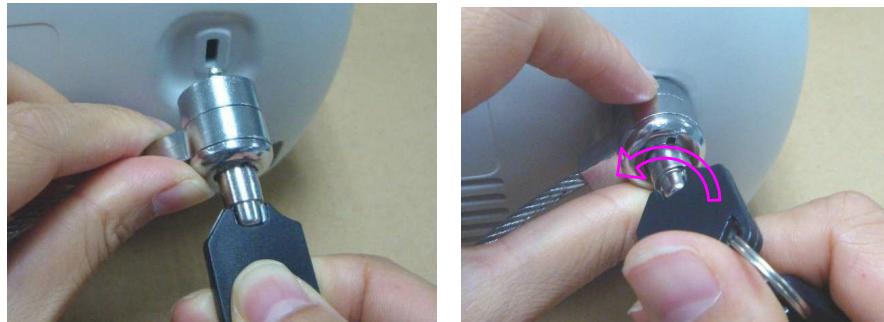
- 1 Press the **Setup** key to open setup menu.
- 2 Press the **Up/Down** key to move the cursor to **Auto Shut Off**, press the **Setup** key.
- 3 Press the **Up/Down** key to move the cursor among options.
- 4 Press the **Setup** key.

3.9.4 Choosing Language

- 1 Press the **Setup** key to open setup menu.
- 2 Press the **Up/Down** key to move the cursor to **Language**, press the **Setup** key.
- 3 Press the **Up/Down** key to select the required language.
- 4 Press the **Setup** key.

3.9.5 Setting Date and Time

- 1 Press the **Setup** key to open setup menu.
- 2 Press the **Up/Down** key to move the cursor to **Real Time Clock**, press the **Setup** key.
- 3 Press the **Setup** key when the cursor stays at **Hour**.
- 4 Press the **Up/Down** key to choose a number from 00 to 23 and then press the **Setup** key to confirm the choice.
- 5 In the same way, choose the Minute from 00 to 59. Choose the Year, Month and Day.
- 6 Move the cursor to **EXIT** and then press the **Setup** key.



3 The lock is securely attached to the main unit. Hitch the device to a stationary object.

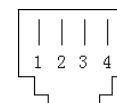


To unlock the main unit,

Insert the key into the lock slot. Apply a certain amount of pressure to the key and then rotate it clockwise. The lock hook is open and you can remove the lock from the main unit.



RJ11 Interface:



- | | |
|---|---------------|
| 1 | Power VCC +5V |
| 2 | GND |
| 3 | Signal Wire |
| 4 | Signal Wire |

3.4.2 Connecting and Disconnecting a Wired Probe

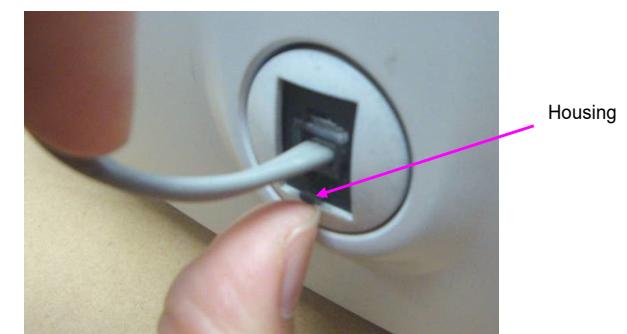
To connect the wired probe to the main unit,

1 Take out the probe cable from package. Insert one modular plug of the cable into the probe socket of the main unit.

2 Insert the other modular plug into the probe socket of the probe.



To disconnect the probe, press the housing of the modular plug and then pull it out.



3.5 Switching On

WARNING

Make sure all the metal parts are linked to the protective earth cord and the power cord is free of defect before switching on the main unit.

CAUTION

To avoid unwanted noise, do not take out or place the probe when the main unit is on. Remember to take out the probe before switching on the main unit, and place the probe after switching off the main unit.

To switch on the main unit,



Pick up the probe and then press the **ON/OFF** key on the main unit.

All the real-time examining menu elements light up in a few seconds. A start-up sound is heard. The Doppler performs a self test by displaying the FHR numerics in a fast speed.

To switch on the wireless probe,



Press the **ON/OFF** key on the wireless probe. The probe indicator lights up in green.

NOTE:

- 1 The **ON/OFF** keys of the wireless probe and the main unit need to be pressed separately.
- 2 The wired probe is ready to use when the main unit is switched on.

3.6 Switching Off

When the examination is finished, switch off the main unit, wipe the remaining gel off the probe with a clean soft cloth and then place the probe back into the holder.

To switch off the main unit, perform any one of these operations:



1) Press the **ON/OFF** key on the main unit.

2) Put the probe into the probe holder.

3) Auto shut off. If the main unit does not receive signal for a period of time, it will be switched off automatically. The auto-shut-off time is preset in the setup menu. Refer to section 3.9.3 *Setting Auto-Shut-Off Time*.

To switch off the wireless probe,



Press the **ON/OFF** key on the wireless probe.

NOTE:

It is recommended to switch off the probe first, and then put the probe into the probe holder.

3.7 Using Earphone

In a noisy environment, the earphone is recommended to hear ideal fetal heart sound.

Insert the earphone plug into earphone socket on the back of the main unit (figure 2-4). The speakers will be muted when the earphone is connected.

WARNING

Turn down the volume before using earphone to your ears.

CAUTION

Accessory equipment connected to the analog and digital interfaces must be certified according to the respective IEC/EN standards (e.g. IEC/EN 60950 for data processing equipment and IEC/EN 60601-1 for medical equipment). Furthermore all configurations shall comply with the valid version of the system standard IEC/EN 60601-1-1. Anybody who connects additional equipment to the signal input connector or signal output connector to configure a medical system must ensure that the system complies with the requirements of the valid version of the system standard IEC/EN 60601-1-1. If in doubt, consult our technical service department or your local distributor.

3.8 Using Security Lock (Optional)

A security lock is provided. You can lock the main unit to a stationary object.

To lock the main unit,

Insert the key into the lock slot. Apply a certain amount of pressure to the key and then rotate it clockwise. The lock hook is open.



Insert the lock hook into security slot on the back of the main unit. Rotate the key anticlockwise to close the lock hook.